REMARKS

Status of the Claims

Claims 1-24 were previously presented. Claims 1, 3-9, 11, 12, 19-21, and 23 were rejected, and claims 2, 10, 13-18, 22, and 24 were objected to.

Claim 12 has been canceled without prejudice or disclaimer. Claims 3, 4, 6, 7, 10, 13, 15, 16, 17, and 19 have been amended. Claims 3, 4, 6, 7, and 10 have been amended to clarify the claims. Claim 13 has been amended to be in independent form. The dependencies of claims 15, 16, and 17 were changed to be dependent upon claim 13 rather than cancelled claim 12. Claim 19 has been amended for clarity reasons. Amended claim 19 is supported in the specification as filed at least at page 45, lines 1-10. No new matter has been introduced by way of any of these amendments. Upon entry of the present amendments, claims 1-11 and 13-24 will be pending. Entry of the amendments and reconsideration of the claims in view of the following comments is respectfully requested.

With respect to the amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Information Disclosure Statement

The Office alleges that the information disclosure statement submitted on September 13, 2006 is in partial compliance with the provisions of 37 CFR 1.97 because it is missing an English

translation or concise explanation of the relevance of the reference. Specifically, the Office did not consider EP 0569802.

Applicants note that EP 0569802 is the EP equivalent of U.S. Patent No. 5,532,266, previously submitted to the Office June 16, 2005. Since the corresponding English version of the document was submitted to the Office, Applicants submit that the previously submitted Supplemental Information Disclosure Statement was in compliance with the provisions of 37 C.F.R. 1.97, and request consideration of the reference and withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 3-9, 11, 19, 20 and 23 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner alleges that the "derivatives" of the compounds in Claims 1, 3-9, 11, 19, 20 and 23 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. For the reasons stated below, Applicants respectfully traverse this rejection.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). An applicant need not describe exactly the subject matter claimed in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. *See, e.g., Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient")." MPEP § 2163.

The term "*derivative*" is well known to those skilled in the chemical art. Merriam-Webster Dictionary defines it as "a chemical substance related structurally to another substance and theoretically derivable from it" or "a substance that can be made from another substance" (see attached). The instant specification as filed builds upon this definition of "derivative" by stating at page 2, lines 19-24 and in Claim 1 that the present invention relates to derivatives of N-methyl-N-[(1S)-1-phenyl-2-((3S)-3-hydroxy-pyrrolidin-1-yl)ethyl]-2,2-diphenylacetamide "with at least one covalently bonded acid" (emphasis added). The specification also states at page 2, line 30 – page 3, line 2 that "the derivative according to this invention preferably comprises at least one acid, or a radical derived from acid, which is bonded to the N-methyl-N-[(1S)-1-phenyl-2-((3S)-3-hydroxy-pyrrolidin-1-yl)ethyl]-2,2-diphenylacetamide by esterification or etherification" (emphasis added). Text of the specification at page 3, line 4 – page 12, line 12 provides further insights into the nature of the acid and its covalent bonding with N-methyl-N-[(1S)-1-phenyl-2-((3S)-3-hydroxy-pyrrolidin-1-yl)ethyl]-2,2-diphenylacetamide.

Thus, the present application describes the invention in enough detail that one skilled in the art of organic chemistry could reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. Therefore, Applicants respectfully submit that this rejection under 35 U.S.C. § 112, 1st paragraph, should be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Enablement of "Preventing or Treating a Disease

Claim 12 was rejected as not being enabled for "preventing or treating a disease". The Examiner alleged that, because Applicants failed to identify diseases or disorders that can be treated by using the product of claim 1, it appears that Applicants are asserting that the embraced compounds would be useful in treating any disease. The Examiner then went through the list of the *In re Wands* factors and concluded that, despite the very high level of skill in the pharmaceutical art, "based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation" (see p. 6 of the OA). Although Applicants disagree with this rejection, Applicants

have canceled claim 12 without prejudice or disclaimer for the sole purpose of advancing prosecution.

Enablement of "Pharmaceutical Active Ingredients"

Claims 19 and 21 were rejected as not being enabled for preparing a pharmaceutical composition with at least one product of claim 1 and at least one further compound selected from excipients, adjuvants and "pharmaceutical active ingredients." The Examiner argued that the specification is unclear as to what pharmaceutical active ingredients Applicants consider suitable to use in preparation of the pharmaceutical composition containing at least one product of Claim 1. For the reasons stated below, Applicants respectfully traverse this rejection.

"To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation'... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

The ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (http://www.fda.gov/CDER/guidance/4011dft.pdf, released July 19, 2000) defines "active pharmaceutical ingredient" as "any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product" and adds that "such substances are intended to furnish

pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body" (p. 41, emphasis added; see attached). The present specification provides that additional active pharmaceutical ingredients may comprise appetite suppressants, vitamins, diuretics or antiphlogistics (i.e. anti-inflammatories; see page 46, line 7 and page 47, lines 1-2).

The Examiner alleges that a skilled artisan would have to conduct an undue amount of *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. Applicants respectfully submit that the Examiner misinterprets the scope of the claims in question. Claims 19 and 21 refer to a method and pharmaceutical composition wherein one or more derivative compounds of Claim 1 is mixed with one or more compounds with known pharmacological activity. The pharmacological effects of the derivative compound(s) and the additional active ingredient(s) may be related to or completely independent of each other. In either event, a skilled artisan would not have to engage in any sort of *in vitro* or *in vivo* screening. All that must be done is routine mechanical mixing of the claimed derivatives with other known pharmacologically active compounds. As Federal Circuit held in *In re Wands*, considerable amount of routine experimentation is permissible if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. The present specification provides ample guidance in regards to preparing said pharmaceutical compositions at page 44, line 31 – page 45, line 10. Thus, no undue amount of experimentation is needed to practice the invention, and therefore Applicants respectfully request that this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Indefiniteness of "Derivative"

Claims 1, 3-9, 11, 19, 20 and 23 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite with regard to the meaning of the term "derivative". The Examiner argued that since "the 'derivative' of the compounds of Claims 1, 3-9, 11, 19, 20 and 23 are not

defined in the claims so as to know the metes and bounds of the claims," the claims are indefinite. For the reasons stated below, Applicants respectfully traverse this rejection.

The definiteness of a patent claim depends on whether one skilled in the art would understand the bounds of the claims when read in light of the specification. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) (citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986)). "A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular [product or method] infringes or not." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

Applicants respectfully submit that the term "derivative" need not be defined in the claims to satisfy the standard of definiteness under 35 U.S.C. § 112, second paragraph. As the Federal Circuit held in *Orthokinetics*, the definiteness of a patent claim depends on whether one skilled in the art would understand the bounds of the claims when read in light of the specification (emphasis added). As Applicants have argued on page 7 of this response, the term "derivative" has a clear definition in the chemical art. Moreover, text of the specification as filed at page 2, line 19 – page 12, line 12 provides much additional guidance as to the nature of the derivative compounds claimed in the present invention. Thus, a person skilled in the art of organic chemistry would have no trouble understanding the metes and bounds of the claims, and Applicants request that this rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Omission of Essential Steps

Claim 19 was rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to an impermissible gap between the steps under MPEP § 2172.01. The Examiner argued that the omitted steps are the reagents used and specific steps of preparing the composition recited in Claim 19. In response to this rejection, Applicants have amended Claim 19 to recite specific mechanical process steps of preparing the claimed pharmaceutical composition. Due to the open language of the amended claim, the list is not exhaustive and may include other steps recited at page 45, lines 7-10 of the specification. However,

with regard to the Examiner's assertion that Claim 19 omits the essential reagents used to prepare the claimed pharmaceutical composition, Applicants respectfully disagree.

The method of Claim 19 as amended refers to "one or more derivatives according to Claim 1, or a salt, solvate, or prodrug thereof, and one or more further compounds selected from excipients, adjuvants and pharmaceutical active ingredients which are different from such derivatives." Compounds that may serve as adjuvants or excipients are well known in the pharmaceutical art, comprising preservatives, stabilizers and/or wetting agents, emulsifiers, salts for modifying the osmotic pressure, buffer substances, colorants and/or aroma substances (see page 46, lines 29–32 of the specification). Compounds that may serve as pharmaceutical active ingredients have already been addressed during the earlier discussion of enablement. The same arguments apply with equal force here. Pharmaceutical active ingredients are well known in the art as any compounds with established pharmacological activity. Thus, since a skilled artisan would easily recognize the metes and bounds of the claims when read in light of the specification, this rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Dependent Claim Objections

Dependent Claims 2-24 were objected to as being dependent upon a rejected based claim. The Examiner recommended rewriting said claims in an independent form to overcome the objection. Applicants request to hold this issue in abeyance until such time the issue of allowability of claim 1 is ultimately resolved.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **613242000800**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 17, 2007

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